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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,001	04/07/2004	Peter Palese	NS104D1C1	9293
36577	7590	09/11/2006	EXAMINER	
JOHNATHAN KLEIN-EVANS			GARVEY, TARA L	
ONE MEDIMMUNE WAY				
GAITHERSBURG, MD 20878			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/821,001	PALESE ET AL.
	Examiner Tara L. Garvey	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 March 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 80-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 80, 83, 84, 90, 91 and 96 is/are rejected.
- 7) Claim(s) 81,82,85-89 and 92-95 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

Claims 80-96 are pending. Receipt is acknowledged of an amendment filed on March 2, 2006 in which claims 1-79 were canceled and new claims 80-96 were added.

***Response to Amendment***

**Claim Objections**

The objection of claims 35-37 is moot in view of cancellation of the claims.

**Claim Rejections - 35 USC § 102**

The rejection of claims 35-48 under 35 U.S.C. 102(e) as being anticipated by Palese et al (U.S. Patent No. 6,544,785 B1) is moot in view of cancellation of the claims.

The rejection of claims 49-79 under 35 U.S.C. 102(e) as being anticipated by Palese et al (U.S. Patent No. 6,649,372 B1) is moot in view of cancellation of the claims.

The rejection of claims 35-48 under 35 U.S.C. 102(a) as being anticipated by Palese et al (U.S. Patent No. 6,544,785 B1) is moot in view of cancellation of the claims.

The rejection of claims 49-79 under 35 U.S.C. 102(a) as being anticipated by Palese et al (U.S. Patent No. 6,649,372 B1) is moot in view of cancellation of the claims.

Double Patenting

The rejection of claims 35-48 under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 4-5, 7-11, 13-16, and 18-19 of prior U.S. Patent No. 6,544,785 is moot in view of cancellation of the claims.

The rejection of claims 49-79 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 6-7, 9, 11-12, 16-17, 19-23, 25-28, 30-32, 38-41, 43, 45-47, and 49 of prior U.S. Patent No. 6,649,372 is moot in view of cancellation of the claims.

***New Grounds of Rejection***

The new rejections were necessitated by applicant's amendment of the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 80 is rejected under 35 U.S.C. 102(a) as being anticipated by Luytjes et al (Cell (1989) volume 59, pages 1107-1113; cited in the IDS submitted October 18, 2004).

Claim 80 is drawn to a composition comprising influenza virus particles that comprise a recombinant vRNA segment.

Luytjes et al teaches a recombinant influenza virus particle that has the coding sequence of the influenza A virus NS gene replace with a chloramphenicol acetyltransferase gene. The influenza virus is produced from a recombinant RNA, which reads on a vRNA because the CAT gene was inserted into the viral RNA sequences for the NS gene segment (abstract, page 1107, right column, second full paragraph, page 1108, Figure 1 and page 1110, right column and page 1111, left column, third full paragraph). Thus, Luytjes et al teaches all that is recited in the instant claim.

Claims 80, 83 and 84 are rejected under 35 U.S.C. 102(a) as being anticipated by Enami et al (PNAS (1990) volume 87, pages 3802-3805; cited in the IDS submitted October 18, 2004).

Claims 80, 83 and 84 are drawn to a composition that comprises an influenza virus particles that comprise a recombinant vRNA segment, which encodes a neuraminidase (NA) protein and the NA protein is modified.

Enami et al teaches an infectious influenza virus that comprises a point mutations that were made in the NA gene from isolate viral RNA. The influenza virus is produced from a recombinant RNA, which reads on a vRNA segment because the RNA for the NA gene segment was isolated from a virus and then modified to produce a recombinant influenza virus (abstract, page 3803, right column to page 3805, left column).

***Double Patenting***

Claim 80 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 47 of U.S. Patent No. 6,649,372. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to a composition of comprising a recombinant influenza virus that has a recombinant vRNA segment.

Claims 80, 90, 91 and 96 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 23-28 and 45-48 of copending Application No.10/713,732 (US 2004/0109877). Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets encompass a composition of recombinant attenuated influenza viruses that are mutated in the NS1 gene of the viral genome, which reads on a recombinant vRNA segment that encodes an NS1 protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Allowable Subject Matter***

Claims 81-82, 85-89 and 92-95 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's

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PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey, Ph.D.  
Examiner  
Art Unit 1636

TLG

SELINE GIAN, PH.D.  
PRIMARY EXAMINER

